

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:  
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## PCT

WRITTEN OPINION

(PCT Rule 66)

Applicant's or agent's file reference  07224.20		Date of Mailing (day/month/year) <b>14 APR 2003</b>  REPLY DUE within 1 months/days from the above date of mailing
International application No.  PCT/US01/50102	International filing date (day/month/year)  21 December 2001 (21.12.2001)	Priority date (day/month/year)  20 December 2000 (20.12.2000)
International Patent Classification (IPC) or both national classification and IPC  IPC(7): A61M 5/00 and US Cl.: 604/181, 187, 191, 201, 203, 205, 264, 272		
Applicant  GILLESPIE, RICHARD D., III		

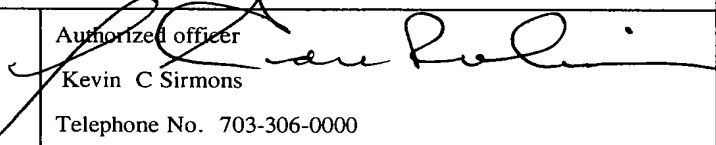
1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
  - I ☒ Basis of the opinion
  - II ☐ Priority
  - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☐ Lack of unity of invention
  - V ☒ Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application
3. The applicant is hereby **invited to reply** to this opinion.
 

**When?** See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~

**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

**Also** For an additional opportunity to submit amendments, see Rule 66.4.  
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 *bis*.  
For an informal communication with the examiner, see Rule 66.6

**If no reply is filed**, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 20 April 2004 (20.04.2004) .

Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer  Kevin C Sirmons Telephone No. 703-306-0000
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703-306-5410

# WRITTEN OPINION

International application No.

PCT/US01/50102

## I. Basis of the opinion

1. With regard to the **elements** of the international application:\*

- ☒ the international application as originally filed
- ☒ the description:  
 pages 1-18, as originally filed  
 pages NONE, filed with the demand  
 pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the claims:  
 pages 19-24, as originally filed  
 pages NONE, as amended (together with any statement) under Article 19  
 pages NONE, filed with the demand  
 pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the drawings:  
 pages 1-9, as originally filed  
 pages NONE, filed with the demand  
 pages NONE, filed with the letter of \_\_\_\_\_.
- ☐ the sequence listing part of the description:  
 pages NONE, as originally filed  
 pages NONE, filed with the demand  
 pages NONE, filed with the letter of \_\_\_\_\_.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/fig NONE

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

# WRITTEN OPINION

International application No.  
PCT/US01/50102

## **V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

### 1. STATEMENT

Novelty (N)	Claims <u>2,3,5,7 and 9-12</u>	YES
	Claims <u>1,4,6 and 8</u>	NO
Inventive Step (IS)	Claims <u>2,3,5,7 and 9-12</u>	YES
	Claims <u>1,4,6 and 8</u>	NO
Industrial Applicability (IA)	Claims <u>1-12</u>	YES
	Claims <u>NONE</u>	NO

### 2. CITATIONS AND EXPLANATIONS

Claims 1, 4, 6 and 8 lacks novelty under PCT Article 33(2) as being anticipated by Van der Wal U.S. Pat. No. 4,820,286.

Van der Wal disclose an automatic mixing and injection apparatus comprising: a housing having a cavity and a proximal and a distal end (figs. 1, 3-6); a syringe assembly within the housing cavity, the syringe assembly further comprising: a first chamber (37); a second chamber (33); a needle (17); a plunger (27); a driver spring (26); as to claim 4, figs. (1, 3 and 4); as to claims 6 (fig. 1, 3, and 4).

Claims 2, 3, 5, 7 and 9-12 meets the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a splitter and splitter connections.

----- NEW CITATIONS -----

WRITTEN OPINION

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PCT/US01/50102

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

**TIME LIMIT:**

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.